

Appendix D: Class II 510(k) Summary
Peri-Guard® Pericardium

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Bio-Vascular, Inc.
2575 University Avenue
St. Paul, MN, USA 55114-1024

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Predicate Device
Supple Peri-Guard.
2. Device Description
Peri-Guard is a tissue patch manufactured from glutaraldehyde cross-linked bovine pericardium and is packaged in a container filled with sterile, non-pyrogenic water containing propylene oxide. The material exhibits excellent tensile strength, bursting strength, and suture retention, making it a useful soft tissue patch. The material exhibits excellent biocompatibility. It has a long history of success as a permanently implanted material since its introduction in 1982.
3. Intended Use
The device is intended for use as a soft tissue patch.
4. Comparison with Predicate Device
Substantially equivalent to predicate device, differing in elasticity (suppleness) only. Submission is made for clarification of labeling only.
5. Nonclinical Tests
Not applicable, material unchanged.
6. Clinical Data
Not applicable, labeling clarification only.
7. Conclusions Drawn from Nonclinical and Clinical Tests
Not applicable.